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KINETIC CONCEPTS, INC.
C/O SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
HAND, MELANIE JO	

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3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,358	TUMEY, DAVID	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 22, 2008 have been fully considered but they are not persuasive.

2. As to arguments under heading A: Applicant argues that Johnson does not suggest a fluid compositional sensing device interposed between the wound dressing/screen means and the vacuum source. The prior art of Saaski was introduced to demonstrate that sensors to detect the partial pressure of oxygen in fluids are known in the art. Partial pressures are correlated with the amount of oxygen in the fluid, i.e. the composition of the fluid. Therefore, Saaski is disclosing that a fluid compositional device sensing the composition of a fluid with respect to its oxygen concentration is known in the art, and thus Johnson does in fact suggest such a sensing device. As to applicant's argument that Saaski does not disclose or suggest any location for the sensing device, Saaski discloses that the device measures partial pressure of oxygen in fluids conveyed by vacuum flow, which would necessitate the placement of the sensing device somewhere along the vacuum path, i.e. between the wound dressing and the vacuum source.

3. As to arguments under heading B.I.: Applicant argues with respect to claim 6 that neither Johnson nor Saaski discloses a fluid compositional device for detecting infection. The limitation "for detecting infection" constitutes functional language. The sensing device of the combined teaching of Johnson and Saaski meets all of the claim limitations as stated in the rejection and is thus fully capable of functioning as a sensing device for detecting infection. Further, the values of pH and pO2 (which the sensor of Saaski provides) are routinely used in the medical art to determine the presence of infection. Applicant further argues that Saaski discloses that

the measure of oxygen is regarded as critical in the clinical assessment of pulmonary cardiovascular function. Pulmonary and cardiovascular are often impaired by infection, e.g. upper respiratory infection and pneumonia. Therefore a sensor that is explicitly disclosed by Saaski as a device that provides a measurement of oxygen level in the lungs or in blood in the cardiovascular system that is critical in the assessment of pulmonary and cardiovascular function is certainly capable of detecting infection by detecting changes in pO_2 in those areas of the body and anywhere else blood or other bodily flui dis present.

4. As to arguments under heading B.II: Neither Johnson nor Saaski discloses a filter upstream of the sensing device along a vacuum path, therefore it is interpreted herein that the fluid compositional characteristics of the wound fluid disclosed by Johnson whose composition with respect to oxygen is detected by the sensor of Saaski is necessarily unfiltered. The balance of arguments under this heading appear to be based upon arguments under heading B.I. addressed *supra*.

5. Applicant's arguments with regard to dependent claims 4 and 7-9 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments presented in the Remarks under headings A, B.I. ands B.II. regarding the rejection of independent claims 1 and 6, which have been addressed *supra*.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19 and 20 (new) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While applicant discloses known sources of infection, e.g. bacteria, and discloses a fluid compositional sensing device that detects the presence of an infection, there is no support in the disclosure as originally filed for a fluid compositional sensing device that detects a source of infection. For examination purposes, the detection of a source of infection as claimed is interpreted as equivalent to the detection of the presence of infection.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 5, 6, 10-13 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (WO 00/59424 A1) in view of Saaski et al (U.S. Patent No. 5,039,491).

With respect to **claim 1:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at

least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Saaski teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Saaski teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO_2 measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Saaski with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Saaski thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With respect to **claim 2:** Johnson does not teach a fluid compositional sensing device. Saaski teaches a fluid compositional sensing device and teaches that such devices are known in the art and include gas chromatograph. Thus the combined teaching of Johnson and Saaski renders the limitation "the fluid compositional sensing device comprises a gas chromatograph" obvious.

The motivation to modify the device of Johnson so as to include a fluid compositional sensing device between the screen means and the vacuum source to measure blood oxygen concentration in the fluid sample conveyed from the body is stated *supra* with respect to claim 1.

With respect to **claim 3:** Johnson does not teach a gas chromatograph. Saaski teaches a fluid compositional device wherein the sensing device further comprises a photo diode operable in optical proximity to fluids being drawn from the wound site towards said vacuum source. Saaski teaches that gas chromatographs are known equivalent devices to the instant optical sensing device having photodiodes, but does not explicitly teach a gas chromatograph that comprises the instant photodiode. The device comprises a cavity chamber for holding a sample that could be replaced by one of ordinary skill in the art with a capillary column as used in gas chromatography. Thus it would be obvious to one of ordinary skill in the art to modify the device of Johnson and Saaski such that the sensing device is a gas chromatograph comprising a photodiode with a reasonable expectation of success to provide a means of sensing oxygen concentration to indicate a patient's cardiovascular and wound site health. The combined teaching of Johnson and Saaski renders the limitation "wherein said gas chromatograph further comprises a photo diode operable in optical proximity to fluids being drawn from the wound site towards said vacuum source" obvious.

With respect to **claim 5:** Johnson teaches a collection canister interposed between said screen means 11 and the vacuum source. Johnson does not teach a fluid compositional sensing device. Saaski teaches a fluid compositional sensing device that detects oxygen level in fluids removed by vacuum flow and thus discloses a fluid compositional sensing device that is placed anywhere along a vacuum path. Thus, while neither Johnson nor Saaski discloses a position for

the collection canister with respect to a fluid compositional sensing device along a vacuum path from the wound dressings/screen means to the vacuum source, the combined teaching of Johnson and Saaski fairly suggests a collection canister between the screen means and the fluid compositional sensing device. The motivation to combine the teachings of Johnson and Saaski so as to also comprise a fluid compositional sensing device is stated *supra* with respect to claim 1.

With respect to **claim 6:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14. Johnson teaches a collection canister interposed between said screen means and said vacuum source. (Page 4, lines 18-21)

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Saaski teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Saaski teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO2 measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen

concentration of the blood conveyed via vacuum flow as taught by Saaski with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Saaski thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With regard to the limitation "for detecting infection", the device of the combined teaching of Johnson and Saaski meets all of the limitations as to a fluid compositional sensing device and thus the instant fluid compositional sensing device is fully capable of detecting infection. With regard to the limitation "said compositional characteristics indicative of said infection within the wound", the instant compositional characteristic, i.e. concentration of oxygen in blood that is within the wound bed fluid, is indicative of infection within the wound inasmuch as insufficient oxygen causes, and is a sign of, infection in a wound bed.

With respect to **claim 10:** The negative pressure therapy device of Johnson further comprises a flexible conduit in the form of material hose 14 for communicating between said screen means 11 and said vacuum source.

With respect to **claim 11:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at

least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Saaski teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Saaski teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO_2 measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Saaski with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Saaski thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With respect to **claim 12:** Johnson does not teach a fluid compositional sensing device. Saaski teaches a fluid compositional sensing device and teaches that such devices are known in the art and include gas chromatograph. Thus the combined teaching of Johnson and Saaski renders the limitation "the fluid compositional sensing device comprises a gas chromatograph" obvious.

The motivation to modify the device of Johnson so as to include a fluid compositional sensing device between the screen means and the vacuum source to measure blood oxygen concentration in the fluid sample conveyed from the body is stated *supra* with respect to claim 1.

With respect to **claim 13:** Johnson does not teach a gas chromatograph. Saaski teaches a fluid compositional device wherein the sensing device further comprises a photo diode operable in optical proximity to fluids being drawn from the wound site towards said vacuum source. Saaski teaches that gas chromatographs are known equivalent devices to the instant optical sensing device having photodiodes, but does not explicitly teach a gas chromatograph that comprises the instant photodiode. The device comprises a cavity chamber for holding a sample that could be replaced by one of ordinary skill in the art with a capillary column as used in gas chromatography. Thus it would be obvious to one of ordinary skill in the art to modify the device of Johnson and Saaski such that the sensing device is a gas chromatograph comprising a photodiode with a reasonable expectation of success to provide a means of sensing oxygen concentration to indicate a patient's cardiovascular and wound site health. The combined teaching of Johnson and Saaski renders the limitation "wherein said gas chromatograph further comprises a photo diode operable in optical proximity to fluids being drawn from the wound site towards said vacuum source" obvious.

With respect to **claim 17:** Johnson teaches a collection canister interposed between said screen means 11 and the vacuum source. Johnson does not teach a fluid compositional sensing device. Saaski teaches a fluid compositional sensing device that detects oxygen level in fluids removed by vacuum flow and thus discloses a fluid compositional sensing device that is placed anywhere along a vacuum path. Thus, while neither Johnson nor Saaski discloses a position for

the collection canister with respect to a fluid compositional sensing device along a vacuum path from the wound dressings/screen means to the vacuum source, the combined teaching of Johnson and Saaski fairly suggests a collection canister between the screen means and the fluid compositional sensing device. The motivation to combine the teachings of Johnson and Saaski so as to also comprise a fluid compositional sensing device is stated *supra* with respect to claim 11.

With respect to **claim 18:** Johnson teaches a collection canister interposed between said screen means 11 and the vacuum source.

With respect to **claim 19:** Johnson does not teach a fluid compositional sensing device. Saaski discloses a fluid compositional sensing device in the form of a sensor that detects the partial pressure of oxygen, which correlates with the amount of oxygen the fluid, i.e. the fluid's composition. The sensing device of Saaski detects a source of infection inasmuch as the device detects the presence of infection by detecting changes in pO_2 in the pulmonary and cardiovascular systems, which infections necessarily have a source. The motivation to modify the device of Johnson to include a fluid compositional sensing device that senses changes in composition of suctioned fluid is stated *supra* with respect to claim 11.

With respect to **claim 20:** Neither Johnson nor Saaski explicitly discloses a source of infection. Saaski discloses that the sensing device senses oxygen amount in the blood (Blood gas), which is a parameter that is critical for assessment of pulmonary function. Therefore Saaski suggests using the sensor to detect changes in pO_2 that are associated with impaired pulmonary function. Since it is universally known that bacteria can cause impaired pulmonary function (e.g.

pneumonia), it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Johnson and Saaski such that the sensing device detects a source/presence of infection wherein the source is bacteria with a reasonable expectation of success to alert a caregiver to impaired pulmonary function detected by change in pO_2 in a timely manner to initiate treatment.

10. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Saaski et al ('491), as applied to claims 1 and 11 above, and further in view of Lewis et al ('440).

With respect to **claim 4:** The fluid compositional sensing device of the combined teaching of Johnson and Saaski is comprised of a sensor array. Lewis teaches sensor arrays that facilitate detecting more than one condition of, and/or analyte in a fluid, thus facilitating the treatment of a patient or wound site for microorganisms causing infection. Therefore, it would have been obvious to one with ordinary skill in the art to modify the device of the combined teaching of Johnson and Saaski so as to substitute the sole sensor with a sensor array as taught by Lewis so as to detect microorganisms causing infection at a wound site in the drainage fluids in addition to monitoring cardiovascular health at the wound site.

11. Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Saaski et al ('491), as applied to claims 6 and 11 above, and in further view of Scherson et al. ('570).

With respect to **Claims 7,15:** The combined teaching of Johnson and Saaski does not teach a sensor embedded in the screen means 11. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor taught by the combined teaching of Johnson and Saaski in the screen means as taught by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site.

12. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Saaski et al ('491) as applied to claim 6 and 11 above, and further in view of Fleischmann (U.S. Patent No. 6,398,767).

With respect to **Claims 8,16:** The combined teaching of Johnson and Saaski teaches a sensing device and a sealing means but does not teach that said sensing device is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 ('767, Fig. 1 and Col. 4, lines 62-64). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to modify the sensor and sealing means taught by the combined teaching of Johnson and Saaski such that the sensor is disposed on the sealing means to detect infections in the atmosphere near the wound area as taught by Fleischmann.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Saaski et al ('491), as applied to claim 6 above, and further in view of Parker et al (U.S. Patent No. 4,955,391).

With respect to **Claim 9:** The combined teaching of Johnson and Saaski discloses a canister and a sensing device outside of the canister but does not disclose a sensing device for sensing infections located in the canister. Parker teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col.5, lines 16-21) to monitor parameters of the fluid collected. This provides additional and more accurate means for detecting infection at the wound site as taught by Parker, therefore it would be obvious to one with ordinary skill in the art to provide the invention of the combined teaching of Johnson and Saaski with the sensing probe of Parker inside of the instant collection canister to provide additional and more accurate means for detecting infection at the wound site.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761